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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/062,794 | 01/31/2002 | Arthur L. Rosenthal | 10177-101 | 3444 |
| 20583 | 7590 | 11/17/2003 | | |
| PENNIE AND EDMONDS 1155 AVENUE OF THE AMERICAS NEW YORK, NY 100362711 | | | | |
| | | | EXAMINER JACKSON, SUZETTE JAMIE | |
| | | | ART UNIT 3738 | PAPER NUMBER |

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/062,794

Applicant(s)

ROSENTHAL ET AL.

Examiner

Jackson J Suzette

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 11 and 12 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Shanley 6,562,065. Shanley discloses the invention as claimed noting figure 11 comprising: A medical device (which is a stent 180) with a plurality of struts (88) and a plurality of non-structural elements integral with the struts (182), wherein the struts and the non-structural elements comprise the biologically active material. (See col. 14, lines 39-57).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shanley. Shanley has been disclosed above with regards to claims 1 and 12 however Shanley does not

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specify the term “hoops” for the shape of the non-structural elements. It is obvious to one having ordinary skill in the art that the “holes” (182) of Shanley can equate to “hoops” because both have a circular shape.

6. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shanley in view of Harish et al. 6,506,437. While Shanley does state the use of biologically active material, Shanley does not specify the drugs. Harish et al. teaches the use of paclitaxel, dexamethasone, and actinomycin (see col. 6, lines 64 and col. 7, lines 5 and 19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the drugs of Harish et al. into the stent of Shanley because they could treat individual dysfunction at the tissue in the vessel site depending upon the individual patients needs.

Allowable Subject Matter

7. Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

8. Applicant's arguments filed 9/3/03 have been fully considered but they are not persuasive. Applicant contends that the non-structural element features of Shanley do not meet the definition as claimed in the specification. However it is the examiner's opinion that Shanley

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does meet the limitations of the claims. In one embodiment of Shanley the non-structural elements are the holes (182) which are “located along the strut” and contain an agent “184” (see col. 14, lines 51-57). In another embodiments of Shanley the non-structural elements can be considered as the polymer coating and an agent (see col. 14, lines 48-50. The structural elements of Shanley have substantially no effect on the mechanical properties of the struts as defined on page 8 of the specification. Applicant further contends “...can be used to increase the surface area of the stent...” (page 8 of amendment). This intended use recitation/functional language carries no patentable weight in the absence of any distinguishing structure. Shanley clearly discloses the structure as claimed and is found to be inherently capable of performing the function.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 703-308-6516.

11. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Suzette J. Jackson
05 November 2003



David H. Willse
Primary Examiner